

ER/DL SPL Team Meeting

Minutes

September 15, 2010

Chair of today's meeting: Pat Cowall

Topics discussed

1. What importers should be listed in the DER file for a foreign establishment? Warren Sunshine
 - Background from Warren: An issue has come up here at Pfizer as to exactly what importer facilities to include in a foreign site registration. His approach has been to include only other registered sites within the U.S. that are responsible for distributing products from the foreign site. What has come into question is whether to also include warehouse sites, that are not otherwise registered within the eList system.
 - Pat's comment: From information gleaned at training sessions, the intent is to facilitate/validate the import of materials by providing all the places that product will be shipped. Homeland security approach.
 - Dragan: You should list all the physical sites that receive the product. This is stated in Lonnie's training materials.
 - Do you have to register the import sites? You don't have to register them in the DER because they aren't part of the manufacturing chain. You just need to provide the DUNS number.
2. How are firms managing a prior approval label change to an existing, posted SPL? Jean Kirkeleit-Davis
 - Background from Jean: Hospira's software creates a nightmare for us when trying to manage prior approval changes to existing, posted SPL files. Because we need to maintain the setID, we end up reverting from one version to another. She would like to know if other software is set up differently or how folks are managing these types of unapproved changes --- for sometimes months or a year before FDA approval is granted. Last version of the SPL supercedes the previous version. They use Vertx by Verify. Cumbersome.
 - Warren (Pfizer): Their software can branch off of the same base version. Branches can come back to the main branch upon approval. XMLabeling.
 - Dragan (Abbott): They are moving to the XMLabeling by Glemser. Currently their software doesn't allow branching either. They export their drafts from the SPL software. When approved, they can import as a new version/draft later.
 - Amy (Merck) – their software is based on MSWord and can make new versions off of any version that they want . i4i
3. Ann (Takeda): Is anyone getting a lot of validation errors on their SPL.
 - ????: They have a subteam working on this-- to their contract manufacturer (CM).
 - Jean: They have asked Lonnie Smith to do a manual override and he has been very responsive.
 - Jean: Lonnie also suggested that (1) use the "old" business operation term, and (2) starting working directly with the CM to correct.
 - Why isn't FDA willing to publish the operations? DUNs wouldn't want their DUNS numbers published along with the business operation terms. This is potentially information that is part of their business asset.

- When you do a download of data from the DFARS site, the DUNS number for the site is not downloaded. Why? Same reason for the above....ie DUNS doesn't want this number easily accessible. Possibility: DUNS number is part of the product that they sell.
4. New LOINC for instructions for use (IFU). When is this expected to be used? Our suspicion is that this is somehow related to devices. We hope to get specific information about this soon.
- R5 has been published but has not been implemented.
 - No specific information has been provided as to how R5 is supposed to be used for devices
 - Outstanding question -- Backwards compatibility -- will it work?
 - We need to stay tuned for further instructions when R5 is implemented.
5. Dragan: Has anybody been successful using the "Link" to the SPL instead of submitted the actual SPL files?
- The link doesn't always work. If it doesn't, you need to contact the SPL site and ask them to initiate it. It magically works 5 minutes later. In reality, somebody behind the scenes have to make it work.
 - Where do you put the link? Terry (GSK) provided the information:
 - FDA has not provided any specific information
 - They usually put it in the cover letter
 - related to an approval letter.
 - Annual Report cover letter, when they have already drug listed it.
 - Putting it in the SPL where you would otherwise put the SPL in the backbone.
6. DUNS information for companies within certain countries is not viewable by FDA.
- The issue relates to a computer issue.
 - Pat will provide a more complete explanation in a future meeting.

In Process topics items:

- Arranging a discussion at a future meeting with someone at CMS -- to discuss how CMS interacts with drug listing (Pat and Terry)
- Process for export products (Pat/Jean)
- Rationale for why it is difficult to have R3s removed manually from Daily Med (Howard/Jean/Pat)
- Communicating with FDA about validation errors -- that result in issues with import, not being able to be compliant with instructions in approval letters, etc. (Warren, Jean, Dragan, and Jessica)
- Create space on wiki to collect questions for future discussions with FDA: DRLS and SPL. (Pat)